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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
10/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,945	PRICE, JOHN J.	
	Examiner	Art Unit	
	Melanie Tyson	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-34* is/are pending in the application.

4a) Of the above claim(s) *13 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-12,14, and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the applicant's amendment received on 07 July 2008. Claim 9 remains cancelled. Claims 13 and 15-21 remain withdrawn from consideration. New claims 32-34 have been added.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: support for claims 32-34 must be incorporated into the specification. In the response filed 07 July 2008, the applicant submitted a table of all the examples disclosed in the specification along with numerical values for calculated percentage differences in diameter between the needle hole and various sized sutures. The applicant is required to incorporate the table into the specification and provide the calculations for all of the values obtained in order to provide proper antecedent basis.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the

applicant failed to disclose the percentage differences in diameter between the needle hole and various sized sutures. Therefore, the claims contain new matter. With further respect to claim 32, even if the calculations in the table provided 07 July 2008 are correct, the applicant did not have something, for instance, 100% greater, which is in the claimed range. With further respect to claim 34, the applicant did not have possession of, for instance, 1%, which is in the claimed range.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A single claim which claims both an apparatus (an armed suture, wherein said first diameter and said third diameter are selected such that there is an annular space between said first end of the needle and said suture) and the method steps of making the apparatus (wherein said first end is swaged inwardly without eliminating said annular space between said first end and said suture) is indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 10 is rejected under 35 U.S.C. 101

based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP 2173.05(p).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 10-12, 14, 22-26, 30, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton (1,558,037). It is noted that sufficient structure has been recited for increasing the bond between the adhesive and the hole (for example, see claim 22). Therefore, 112, sixth paragraph, has not been invoked.

Morton discloses an armed suture (see entire document) comprising a needle (1) having first (top end) and second (pointed end) opposed ends and a blind hole (2) formed in the first end and extending longitudinally, the hole including a sidewall and a

bottom wall (flat portion) disposed at a location intermediate the opposed ends, wherein the first end is considered to extend to a position adjacent the bottom wall, and having a first diameter proximate the first end (top end) and a second diameter distal to the first end that is greater than the first diameter (for example, see Figure 3 and page 1, lines 29-31), and a suture (4) having an end inserted into the hole and having a third diameter, wherein the first diameter is greater than the third diameter (for example, see page 2, lines 29-32). The first diameter is greater than the third diameter by a factor that allows the hole to accommodate the insertion of a range of differently-sized sutures therein in that a range of differently-sized sutures that are smaller than the suture shown in Figure 3 may be utilized.

Morton discloses an adhesive (cement) that upon setting adheres to the suture material anchoring the suture in the hole (for example, see page 2, lines 34-40), thus inherently discloses an adhesive having a viscosity when uncured (or unset) permitting the suture to be inserted into the hole and when cured (when set or dried) bonds the suture to the needle forming a mechanical lock therewith. Morton's adhesive extends from the first end at a position adjacent the neck portion to the bottom wall of the hole substantially surrounding the end of the suture within the hole (for example, see Figure 3). Morton further discloses an alternate embodiment in which the inside of the hole is scarified (or roughened bond increasing means; see claims 1 and 22) in such a matter as to provide adequate anchorage of the suture therein (for example, see page 2, lines 60-63). It is well within the general knowledge of one having ordinary skill in the art to combine prior art elements to yield predictable results. Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to provide the blind hole of Morton with a roughened surface and an adhesive. Doing so would provide greater anchorage between the hole and adhesive, in turn enhancing anchorage between the suture and the hole, thus further reducing the risk of the suture detaching from the needle during use.

Regarding claim 10, Morton discloses the first end is swaged inwardly so that it is only slightly greater than the diameter of the suture (for example, see page 2, lines 29-32). The space between the cylindrical recess and cylindrical suture is considered to be an annular recess. Regarding claim 12, Morton does not disclose the hole is polished after scarified. Therefore, it is inherent that the hole is unpolished in this embodiment. Otherwise, the advantages of scarifying would be eliminated in that polishing would provide a smooth surface. Regarding claim 14, Morton discloses the suture may comprise a suture that is commonly employed in surgery (for example, see page 2, lines 54-55), and monofilament sutures are commonly used in surgery (for example, see Dery's patent 3,394,704; column 3, lines 16-18). Regarding claim 31, Morton discloses the hole is a truncated cone tapering toward the neck (for example, see page 1, lines 27-31), thus comprises a bottle-shape. Morton further discloses the adhesive conforms to the shape of the recess when set (for example, see page 2, lines 38-39), thus the adhesive also comprising a bottle-shape.

Claims 11 and 23-25 are being treated as product by process limitations, in that "said suture hole is formed by laser drilling," "said roughened portion is reamed," "said roughened portion is laser drilled," and "said roughened portion is etched," refers to the

process of forming the suture hole and its surface and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, an armed suture as described above wherein the suture hole is formed by laser drilling, and the roughened surface is reamed, laser drilled, or etched, is directed to the method of making the armed suture hole and its roughened surface and not to the final product made. It appears that the product disclosed by Morton would be the same or similar as that claimed; especially since both applicant's product and the prior art product have the same final structure of an armed suture comprising a suture hole having a roughened surface.

Regarding claims 26 and 30, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the roughened bottom wall with a conical shape and tip. Applicant has not disclosed that a conical shape and tip provides an advantage, is used for a particular purpose, or solves a stated problem and it appears the prior art shape would perform equally well. Therefore, it would have been obvious to modify the shape of Morton's bottom roughened wall to obtain the invention as specified in claims 26 and 31. Furthermore, Morton discloses the hole may be drilled

and metal drills having fluted tips that conventionally form suture holding bores with cone-shaped bottom walls are well known in the art (for example, see Messer et al.'s patent 3,910,282).

Regarding claims 32-34, Morton fails to disclose by how much the first diameter is greater than the third diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size of Morton's suture and/or the size of Morton's hole in order to obtain the ranges claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

8. Claims 2-8 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton as applied to claim 1 above, and further in view of Korthoff et al. (5,156,615). Morton discloses a device as described above, however, fails to disclose the adhesive is curable as claimed or that the adhesive is cyanoacrylate.

Korthoff discloses bonding a suture attached to a needle using adhesives (see entire document). With respect to claims 2-8, Korthoff teaches that cyanoacrylate (which is curable by exposure to electromagnetic radiation, such as UV light, and further curable by a second curative agent, such as water or heat) is a preferred adhesive for bonding the suture within a hole in the needle, since cyanoacrylate possesses excellent adhesive characteristics (for example, see column 9, lines 18-23). It is well within the general knowledge of one having ordinary skill in the art to substitute one known element for another to obtain predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute

the adhesive disclosed by Morton with cyanoacrylate as taught by Korthoff. Doing so would further enhance the bond, thus further reducing the risk of the suture detaching from the needle during use.

With further respect to claims 27-29, the applicant admits that a low viscosity, UV-curable, cyanoacrylate adhesive having a cyanoacrylate secondary cure mechanism is well known and is available under the name LOCTITE Product 4302. It is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try the cyanoacrylate adhesive having the cyanoacrylate secondary cure mechanism as claimed in order to try and further enhance the bond between the suture and needle.

Response to Arguments

9. Applicant's arguments filed 07 July 2008 have been fully considered but they are not persuasive. The applicant argue primarily that the prior art applied fails to disclose each and every element as claimed. The examiner respectfully disagrees.

The applicant argues that the close fit of Morton's suture would prevent the adhesive from extending from the bottom of the recess all the way up to its neck. Since there is no adhesive at the neck of the recess, it follows that the adhesive can not surround the suture at the neck. However, it is the examiner's position that the applicant has not recited that the adhesive extends to and surrounds the suture at the neck. Claim 1 simply recites an adhesive "extending from the first end to said bottom wall of

said hole and substantially surrounding said end of said suture within said hole." This language does not require the adhesive to extend all the way up to the neck portion. This language is interpreted as requiring the adhesive to extend from any portion of the first end to the bottom wall. The first end extends from the top of the hole to a portion adjacent the bottom wall of the hole, wherein the bottom wall is considered to be part of an intermediate portion. Figure 3 clearly shows that the adhesive extends from at least a portion of the first end to the bottom wall of the hole. Therefore, Morton discloses an adhesive extending as claimed.

The applicant further argues that Morton discloses the diameter of the hole is only slightly greater than the diameter of the suture, thus the hole is not suited to accommodate the insertion of a range of differently-sized sutures. However, it is the examiner's position that the hole is suited to accommodate the insertion of a range of differently-sized sutures that are smaller than Morton's suture.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
October 20, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773